

## **REMARKS**

The Office Action of April 21, 2006 has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested in view of the amendments and remarks presented in this response.

Claims 1-2, 4-13, 15-23 and 25-28 are pending in this application. Upon entry of this amendment, claims 1, 11, 25, and 28 are amended. In order to expedite prosecution of the present application, and without waiving any rights to pursue future claims directed to the combination, independent claims 1, 11, and 25 are amended to recite either polybutyleneterephthalate (PBT) or polyethyletherketone (PEEK), not the combination. Claims 11, 25, and 28 have been amended for clarity with respect to the recitation of the growth-enhancing composition.

### **Priority Date**

The Office Action states that the “priority date of the present [sic] remains January 2, 2002.” This is the filing date of the present application. For at least all of the reasons set forth in the Response to Office Action filed February 13, 2006, Applicants submit that the application should be afforded the benefit of the priority date of the provisional application, *i.e.*, January 2, 2001. The provisional application complies with the requirements of 35 USC § 112, and the present application properly claims the benefit of the provisional application in the specification of the present application. With respect to the pending claims, Applicants also respectfully submit that the claims are entitled to the filing date of the provisional application, *i.e.*, January 2, 2001. The Office Action states that the combination of PEEK with PBT as claimed is not disclosed in the provisional application. As noted above, amended claims 1, 11, and 25 are directed to either polybutyleneterephthalate or polyethyletherketone, not the combination. Thus, Applicants respectfully submit that the priority date of the application, as well as the pending claims, is January 2, 2001.

### **Claim Objections**

Claims 11-13, 15 and 25-28 are objected to because of an informality in the claims. As noted above, claims 11 and 25 have been amended for clarity and now are presented in Markush format. Withdrawal of this objection is respectfully requested.

### **Claim Rejections Under 35 USC §103**

Claims 1-2 and 4-7 stand rejected under 35 USC §103(a) for being unpatentable over Walish et al. (Symposium Y) in view of DeBruijn et al. (U.S. Patent No. 6,228,117) in further view of Vyakarnam et al. (U.S. Patent No. 6,534,084). Further, claims 6, 8, 11-13, 15 and 25-28 stand rejected under 35 USC §103(a) for being unpatentable over Walish et al., in view of DeBruijn et al., in further view of Vyakarnam et al., as above, in further view of Kumar (U.S. Publication No. 2002/0127391). These rejections are respectfully traversed.

For at least the reasons set forth above, Applicants submit that the effective filing date of the pending claims is January 2, 2001. Applicants further submit that Walish et al., which appears to have been published on April 24-26, 2000, and Kumar, which has a filing date of December 15, 2000 and a publication date of September 12, 2002, are not prior art under 35 USC 102(b). To the extent it should be necessary, Applicants are prepared to submit an affidavit pursuant to 37 CFR 1.131 and/or 1.132 to establish invention prior to the effective date of the Walish et al., which was authored in part by the inventors of the present application, as well as the Kumar publication.

Even if Applicants do not antedate Walish and/or Kumar, the combination of the cited references does not disclose, teach or suggest the claimed invention. Briefly, independent claim 1 relates to a biocompatible implant comprising a matrix of a composition selected from the group consisting of polybutyleneterephthalate and polyethyletherketone and having a pore size of between about 150 to about 400  $\mu\text{m}$  and a porosity of between about 50% to about 60% by volume. Independent claim 11 relates to a biomedical implant that includes a porous structure formed from a thermoplastic material selected from the group consisting of polybutyleneterephthalate and polyethyletherketone, where the porous structure has a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400  $\mu\text{m}$ . The implant also includes a composition for enhancing the rate of bone growth including a polymer material selected from the group consisting of polylactic acid, polyglycolic acid, polylactic acid-polyglycolic acid copolymer, polycaprolactone, and combinations thereof. Independent claim 25 relates to methods of repairing or replacing tissue that include forming a biocompatible substrate including a polymer composite selected from the group consisting of polybutyleneterephthalate and polyethyletherketone, and a growth-enhancing composition including a polymer material selected from the group consisting of polylactic acid, polyglycolic

acid, polylactic acid-polyglycolic acid copolymer, polycaprolactone, and combinations thereof. The biocompatible substrate has a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400  $\mu\text{m}$ .

Importantly, Walish et al. do not disclose implant materials that include PBT or PEEK. Walish et al. disclose porous implants made from slowly-degradable polyesters that are impregnated with a biodegradable polyester/hydroxyapatite blend. Walish et al. do not disclose PBT or PEEK, or that the materials have any specific pore size or porosity. Walish et al. also do not disclose that the implants also include compositions for enhancing the rate of bone growth including polylactic acid, polyglycolic acid, polylactic acid-polyglycolic acid copolymer, polycaprolactone, a calcium source and combinations thereof.

DeBruijn et al. disclose a device for facilitating cell growth *in vitro* prior to implantation of the device. DeBruijn et al. disclose that the device is made of a thermoplastic polymer and provide examples of a PEO/PBT copolymer. DeBruijn et al. teach that the osteoinductive properties of the device are the result of *in vitro* formation of bone matrix (see, e.g., Col. 4, lines 17-21; Col. 9, lines 28-32). Moreover, in Example 1, DeBruijn et al. teach that the effectiveness of the copolymer to calcify and form a mineralized extracellular matrix decreased as the amount of PBT in the copolymer increased (see, e.g., Col. 5, line 50 – Col. 6, line 3). Thus, DeBruijn et al. fail to disclose a device made of PEEK or PBT alone, and instead teach away from a device made of PBT alone.

Vyakarnam et al. disclose an interconnected, open cell porous foam, such as made of caprolactone. Thus, Vyakarnam et al. fail to disclose a structure made of PBT or PEEK.

Kumar discloses a coating for a substrate, such as a plate, where the coating includes a ceramic in a resorbable polymer binder. The ceramic preferably is a phosphate, carbonate, bicarbonate or sulfate, and the polymer is composed of lactic acid, glycolic acid, amides, anhydrides, orthoesters, and dioxanones. Thus, Kumar fails to disclose a structure made of PBT or PEEK.

Accordingly, Walish et al., DeBruijn et al., Vyakarnam et al. and Kumar, either alone or in combination, do not disclose, teach or suggest the invention claimed in independent claims 1, 11, and 25, as well as any of the dependent claims, and the claims pending in the present application are not obvious. In view of the above, reconsideration and allowance of the pending claims are respectfully requested.

### **CONCLUSION**

In view of the above amendments and remarks, prompt reconsideration and full allowance of the claims pending in the subject application are respectfully requested. All rejections have been addressed. Applicants respectfully submit that the instant application is in condition for allowance and respectfully solicit prompt notification of the same.

The Commissioner is authorized to debit or credit our Deposit Account No. 19-0733 for any fees due in connection with the filing of this response.

The Examiner is invited to contact the undersigned at the number set forth below should the Examiner believe that a further conversation would be useful in the prosecution of this case.

Respectfully submitted,

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By:           / Rebecca P. Rokos/            
Rebecca P. Rokos  
Registration No. 42,109  
BANNER & WITCOFF, LTD.  
10 South Wacker Drive  
Suite 3000  
Chicago, IL 60606  
Telephone: 312-463-5000  
Facsimile: 312-463-5001